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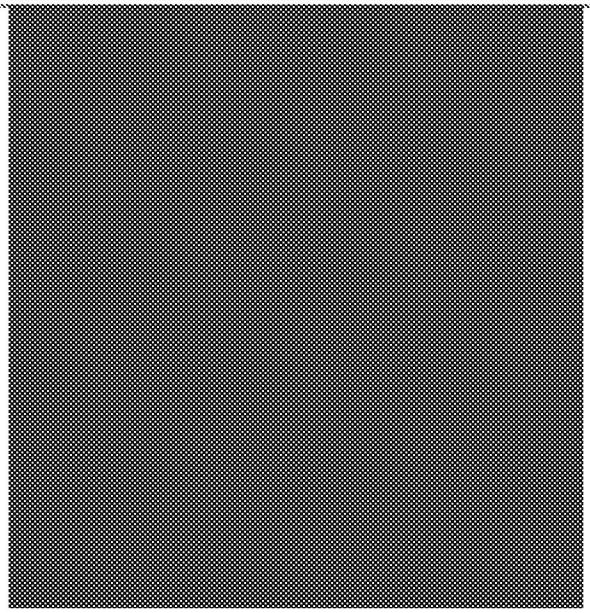

Giant Eagle Pharmacy Controlled Substances Manual

Tsipakis
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3/17/2021

Giant Eagle Pharmacy Controlled Substances Manual

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Statement of Purpose

The abuse of prescription drugs is epidemic in the United States. According to the Center for Disease Control (CDC), prescription drug abuse is the fastest growing in the United States. Deaths from prescription drug overdoses exceed deaths from auto accidents. Over 20% of Americans admit to abusing prescription drugs and they are now the recognized "gateway" drugs to heroin and other illegal drug abuse.

It is our responsibility both as a company and as healthcare professionals to do all we can to curb the misuse of prescriptions drugs. In addition, the DEA in its efforts to control the illegal use of prescription drugs is holding pharmacists ***personally*** accountable for their decisions and actions when dispensing controlled substances. Each of us has a professional and moral obligation to protect the health of our patients and the integrity of our conduct for both ourselves and Giant Eagle.

The purpose of this manual is to define and standardize how we manage controlled substances including:

- Dispensing
- Ordering
- Receiving
- Auditing
- Returning/removing from inventory (outdates)
- Investigating suspected diversion/theft

Giant Eagle's Promise of Support

Giant Eagle supports the professional judgment of each Pharmacist Team Member. If after performing required due diligence, any pharmacist refuses to fill a prescription for a medication due to concerns of validity and/or misuse, Giant Eagle will support the decision and no corrective measures will be taken against the pharmacist. In addition, no other Team Member may in any way try to coerce a Giant Eagle pharmacist to fill a prescription that in his/her professional judgment and after due diligence is likely to be misused. Any coercion will be considered an ethics violation and will be reported and disciplined according to the ethics standards of Giant Eagle.

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Legal Documents

Most of the legal requirements for management of controlled substances are found in the following documents:

- Controlled Substance Act
- Pharmacist Manual
- State Regulations
- State Prescription Monitoring Programs

Controlled Substance Act

The controlled Substance Act was enacted in 1970. The legislation created five schedules used for controlled substances and the requirements for each schedule. The Controlled Substance Act also was responsible for the creation of the Drug Enforcement Agency (DEA) to enforce the requirements defined by the act.

Pharmacist Manual

The Pharmacist Manual is published by the DEA and is an information outline of the Controlled Substance Act. The purpose of the Pharmacist Manual is to clarify and "assist pharmacists in their understanding of the Federal Controlled Substance Act and its implementing regulations as they pertain to the pharmacy profession."

State Regulations

The state legislatures and State Boards of Pharmacy have regulations that are required in each state. It is the responsibility of each pharmacist to know and follow both federal and state requirements in the practice of pharmacy. If there is anytime the regulations differ, the more stringent requirement should be followed.

State Prescription Monitoring Programs

One of the difficulties in identifying prescription drug misuse is the ability for abusers to go to multiple pharmacies to have prescriptions filled. To help track prescription drug use, states have developed prescription monitoring programs. Controlled prescriptions are reported to a central data base that can be reviewed by any pharmacy in the state. Examples of prescription monitoring programs include:

- Ohio Automated RX Reporting System (OARRS)
- Pharmaceutical Accountability Monitoring System (PAMS) – currently in the legislature in Pennsylvania
- West Virginia Prescription Monitoring Program (WV PMP) – currently accessible by law enforcement only
- Prescription Drug Monitoring Program (PDMP) – currently in development in Maryland

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Due Diligence

Due diligence can be defined as "the care a reasonable person should take before entering into an agreement or transaction with another party" (Investopedia.com).

In regard to filling prescriptions for controlled substances, due diligence includes verifying the following:

- The prescription is valid (including for a legitimate medical purpose)
- The prescription is appropriate (dosage and quantity are reasonable for the patient's diagnosis)
- The prescription is timely (on schedule to be filled based on previous prescription history)

While it is the responsibility for the prescriber to write controlled substance prescriptions legally and responsibly, there is an acknowledged corresponding responsibility for the pharmacist to "exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription" (Pharmacist's Manual). A pharmacist who knowingly dispenses a prescription that is not valid is subject to the same legal penalties as a prescriber. Please see the "Valid Controlled Substance Prescription" section on the following pages for guidance.

It is also our responsibility to ensure all patient and prescriber information is accurate and current. Patient addresses and contact numbers must be regularly reviewed and updated. Prescriber information must be kept updated including DEA number changes when interns are licensed individually rather than under a hospital DEA.

In addition to determining if a prescription if valid, we have a responsibility to determine if it is written ethically and in the best interest of the patient's health. Prescriptions written for very large dosages and/or quantities are more at risk for misuse and should be scrutinized accordingly. Verify the reason for the large dosage or quantity with the prescriber. If the patient's health requires larger doses, record the reason on the prescription or as an image note.

Frequent signs of misuse of prescription medications include multiple prescribers and early refills. Do not refill prescriptions for controlled substances early (before 75% use) without reason and documentation. If a patient is receiving prescriptions for controlled substances from multiple prescribers, ensure each prescriber is informed of the full medication profile of the patient.

Giant Eagle will support the professional judgment of pharmacists when deciding whether or not to fill prescriptions for controlled substances, but requires due diligence as part of the judgment process. The DEA also reviews patterns of due diligence when auditing pharmacist's dispensing history.

We have a responsibility to our patients, professions and company to complete due diligence when filling prescriptions for controlled substances. While it is inevitable that some prescriptions filled will be misused or not valid, due diligence minimizes the number of invalid or misused prescriptions dispensed and decreases the likelihood of a patient accidently overdosing on a prescription medication.

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

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Valid Controlled Substance Prescriptions

Purpose of Issue

A prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. A prescription written outside the scope of the prescriber's practice (i.e. a dentist writing a prescription for back pain) is not valid and cannot be filled. Prescriptions cannot be written for a prescriber to dispense to patients from his/her practice. Controlled substance prescriptions cannot be delivered or shipped to individuals in other countries without proper authorization.

Prescription Requirements

A prescription for a controlled substance must be dated and signed on the date issued. It must be written in ink, indelible pencil or typed and manually signed by the practitioner or agent. It must include the following:

- Patient's full name and address
- Drug name
- Drug strength
- Dosage form
- Quantity prescribed
- Directions for use
- Number of refills authorized (if any)
- Prescriber's full name and address
- Prescriber's DEA number

Schedule III – V Prescriptions

Prescriptions for Schedule III – V can be received via written prescription, oral prescription or fax. While it is legal to receive Schedule III – V prescriptions via electronic prescribing, we are not registered to accept them at this time. If any of the required elements are missing on a Schedule III – V prescription, the prescriber can be contacted for clarification and the information recorded on the prescription or as an image note with the pharmacist acting as the prescriber's agent. Schedule III – V prescriptions can be refilled up to a maximum of five times (based on the original prescribed quantity) or for six months, whichever comes first. "PRN" is not an acceptable refill designation for a Schedule III – V prescription. Prescriptions for Schedule III – V can be transferred only one time between pharmacies including two Giant Eagle pharmacies.

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Schedule II Prescriptions

Schedule II prescriptions may only be received via written prescription and must be signed by the prescriber except in cases of emergency dispensing (see requirements listed on following page). A pharmacist can call a prescriber for clarification of a Schedule II prescription but cannot alter the patient name, control substance prescribed or prescriber's signature (a new prescription must be acquired if any of these need changed/edited). The dosage form, strength, quantity or directions for use may be changed after consultation with the prescriber, but must be documented on the hard copy or image note. Prescriptions for Schedule II medications cannot be refilled or transferred.

Partial Filling of Schedule II Prescriptions

Schedule II prescriptions can be partially dispensed if the pharmacy is unable to supply the full quantity. The amount dispensed must be noted on the face of the prescription or recorded as an image note. The balance of the prescription must be dispensed within 72 hours or the balance of the prescription is void. The pharmacist must inform the prescriber if the full amount or a schedule II prescription is not dispensed.

Multiple Prescriptions for Schedule II Medications

A prescriber may issue multiple prescriptions for a Schedule II medication authorizing the patient to receive up to a 90 day supply of medication. Each prescription must be written on a separate prescription blank and follow all requirements for a Schedule II prescription. The prescriber must specify fill dates for the additional prescriptions.

Emergency Dispensing of Schedule II Prescriptions

A prescriber may phone in a prescription for a Schedule II medication for emergency dispensing. For a situation to require an emergency dispensing of a Schedule II medication, all of the following must apply:

- The patient requires immediate administration of the medication for proper treatment
- No alternative treatment is available (including another non Schedule II medication)
- It is not possible for the prescriber to provide a written prescription at that time

Emergency prescription requirements include:

- The amount prescribed must be limited to the amount needed during the emergency period (until a written prescription can be received)
- The prescription order must be written by the pharmacist and include all necessary elements except the prescribers signature
- The pharmacist must know the prescriber or make reasonable attempts to confirm the prescriber is a registered practitioner
- Within seven days, the pharmacist must receive a written, signed prescription with "Authorization for Emergency Dispensing" and the date of the oral prescription written on the face of the received prescription
- If a written prescription is not received within seven days, the pharmacist must notify the DEA

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Faxing Schedule II Prescriptions

A prescriber may fax a Schedule II prescription so it can be prepared by the pharmacy, but the hard copy must be presented to the pharmacy before the medication can be dispensed. There are three conditions when it is legal to fax a Schedule II prescription and it may serve as an original prescription without a requirement to bring in a hard copy before dispensing.

- Prescribers writing prescriptions for Schedule II medications to residents of Long Term Care Facilities
- Prescribers writing prescriptions for patients enrolled in a hospice care program certified by Medicare
- Prescribers writing prescriptions for a Schedule II narcotic to be compounded for direct administration to a patient by injection

Prescriber Requirements to Prescribe Controlled Substances

A prescription for a controlled substance must be written by an authorized prescriber who is:

- Authorized to prescribe controlled substance by jurisdiction in which the practitioner is licensed to practice, and
- Registered with the DEA or exempted from registration (i.e. Public Health Service, Federal Bureau of Prisons, military practitioners), or
- An agent or employee of a hospital or other institution acting in the normal course of business or employment and acting under the registration of the hospital or other institution (see requirements on next page)

Practitioner's Use of a Hospital DEA Number

Practitioners (i.e. interns, residents, etc.) may use a hospital's DEA number in lieu of individual registration if they meet the following requirements:

- The prescribing is in the usual course of professional practice
- The prescriber is authorized to do so by the state in which they practice
- The prescriber acts only within the scope of employment
- The prescriber is authorized by the hospital or institution under its registration and assigns a specific internal code number to each prescriber
    - The internal code number is typically three digits and should be placed after the hospital's DEA number on the prescription (i.e. AB1234562-012)
- The hospital or other institution maintains a listing of assigned codes and can verify the prescriber's identity and authorization

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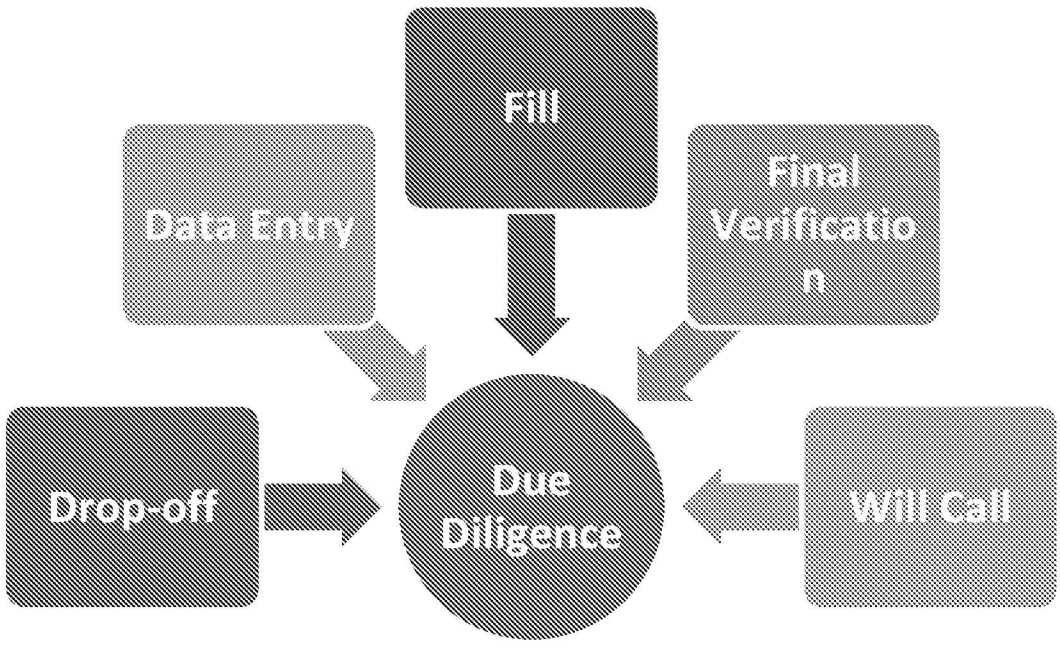
Filling Prescriptions for Controlled Substances - Due Diligence

When filling and dispensing controlled substance prescriptions, we must evaluate if the prescription is valid and necessary and take precautions to ensure accuracy and protection from misuse.

Filling prescriptions for controlled substances can be broken down to several steps:

- Drop-off or other method of receiving the request to fill a controlled substance prescription
- Data entering a controlled substance prescription
- Filling (counting/pouring) a controlled substance prescription
- Final Verification of a controlled substance prescription
- Selling a controlled substance prescription (Will Call)

Throughout the filling and dispensing process, we must ensure we are completing due diligence to verify the prescription is valid, for a reasonable dosage and quantity and on schedule to be filled/refilled based on previous prescriptions.



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Drop-off

The first step in the dispensing process for a controlled substance prescription is determining if it is appropriate to be filled. Due diligence is the responsibility of every Pharmacy Team Member. If a technician or intern is unsure about the validity of a prescription, or questions if it is appropriate to fill, ALWAYS involve the appropriate pharmacist. The request to fill or refill a prescription can be received via a number of pathways including:

- Drop-off station in the pharmacy/drive-thru
- Prescriber phone/fax/IVR message
- Patient phone/IVR refill request

Drop-off Station/Drive-thru

When a written prescription is received at the pharmacy by a customer, due diligence includes determining if the prescription should be filled or if it will need to be verified with the prescriber.

Due diligence could include determining any/all of the following:

- Is the prescription for a regular patient?
- Does the patient receive medications other than controlled substance prescriptions and common "companion" prescriptions such as antibiotics
- Does the patient receive controlled substance prescriptions from multiple prescribers?
- Is the patient requesting an early fill of a controlled substance prescription?
- Is the prescription from a local prescriber?
- Is all necessary information included on the prescription?
- Does the prescription look altered in any way?
- Is the prescription written for a dose within normal dosing range and a reasonable quantity?
- Are there any "red flags" or reasons to be suspicious of the patient or prescription (see red flags list at the end of this section)?

Prescriber Phone/Fax/IVR Message

Frequently, prescriptions for controlled substances are received in the pharmacy from the prescriber. A major concern is determining if the prescriber is a valid practitioner.

Due diligence could include determining any/all of the following:

- Is the prescription for a regular patient?
- Does the patient receive medications other than controlled substance prescriptions and common "companion" prescriptions such as antibiotics
- Does the patient receive controlled substance prescriptions from multiple prescribers?
- Is the patient requesting an early fill of a controlled substance prescription?
- Is the prescription from a local prescriber?
- Is all necessary information included on the prescription/message?
- Is the prescription written for a dose within normal dosing range and a reasonable quantity?
- Are there any "red flags" or reasons to be suspicious of the prescriber (see red flags list at the end of this section)?

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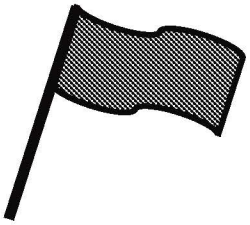
Patient Refill Phone/IVR Request

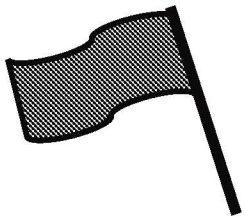
Due diligence is required when refilling prescriptions as well as when filling them for the first time. When a patient requests a refill, a major concern is determining if the medication is being used as intended.

Due diligence could include determining any/all of the following:

- Is the patient requesting an early refill of a controlled substance prescription?
- Does the patient ask questions such as, "what is the earliest date I can get my prescription refilled?"



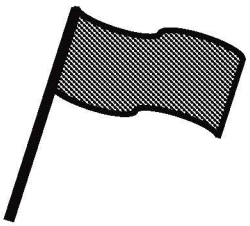
RED FLAGS FOR DROP-OFF



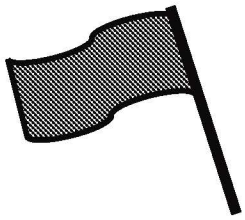
The following are suspicious behaviors or "clues" that additional due diligence such as contacting the prescriber for verification may be necessary.

Patient

- Patient appears nervous or over friendly
- Patient requests brand or a specific manufacturer or generic
- Patient claims to have no prescription insurance coverage
- Patient insists on waiting and "hovers" near the pharmacy
- Patient is new to the pharmacy (including Rx.com)
- The patient is not local (especially out of state to possibly avoid state prescription monitoring programs)
- Patient's address is unable to be confirmed by the US Postal file when the patient is added to the computer system
- Patient asks to only fill the controlled substance prescription and doesn't need any companion scripts



Red Flags for Drop-off (continued)



The following are suspicious behaviors or "clues" that additional due diligence such as contacting the prescriber for verification may be necessary.

Prescription

- The prescriber or prescriber's handwriting is unfamiliar or different than typical (may have stolen a prescription blank)
- A prescription from a prescription pad it not "squared" having uneven edges and has no roughness or evidence of glue along the top (may have been printed on a PC and cut apart)
- A prescription from a prescription pad that has an unusual texture (could be photo copied or the original information could have been washed off with acetone)
- The prescription looks like it was photo-copied
- There are multiple handwritings or inks used (may have been altered)
- Non-standard abbreviations are used
- Illegal number of refills (may have been altered)
- Out of area/out of state prescriber
- Multiple controlled substance prescriptions being requested simultaneously
- Prescriptions for very large quantities of controlled medications

Physician (Phoned or IVR Prescriptions)

- Person giving the prescription sounds unsure or nervous
- Person giving the prescription is unable to provide all requested information

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

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Data Entry

Data entry provides multiple opportunities for due diligence since the patient's profile is available during the process. Due diligence is the responsibility of every Pharmacy Team Member If a technician or intern is unsure about the validity of a prescription, or questions if it is appropriate to fill, ALWAYS involve the appropriate pharmacist. Data entry can involve either a new or refill prescription.

New Prescriptions

When data entering a new prescription, due diligence includes determining if the prescription should be filled or if it will need to be verified by contacting the prescriber.

Due diligence could include determining any/all of the following:

- Is the prescription for a regular patient?
- Does the patient receive medications other than controlled substance prescriptions and common "companion" prescriptions such as antibiotics
- Does the patient receive controlled substance prescriptions from multiple prescribers?
- Is the patient requesting an early fill of a controlled substance prescription?
- Is the prescription from a local prescriber?
- Is all necessary information included on the prescription?
- Does the prescription look altered in any way?
- Is the prescription written for a dose within normal dosing range and a reasonable quantity?
- Is the prescription billed to cash despite evidence of insurance coverage for the patient?
- Is the prescription filled with a DAW 2?
- Are there any "red flags" or reasons to be suspicious of the prescription (see red flags list at the end of this section)

Refill Prescriptions

Due diligence is required when refilling prescriptions as well as when filling them for the first time. When a patient requests a refill, a major concern is determining if the medication is being used as intended.

Due diligence could include determining any/all of the following:

- Is the patient requesting an early refill of a controlled substance prescription?
- Did the prescription come from the "Refill Too Soon" queue/file?

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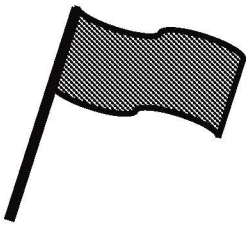
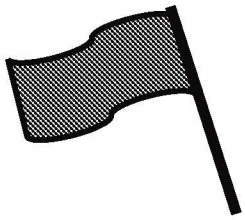


Red Flags for Data Entry



The following are suspicious behaviors or "clues" that additional due diligence such as contacting the prescriber for verification may be necessary.

- Patient is new to the pharmacy (including Rx.com)
- The patient is not local (especially out of state to possibly avoid state prescription monitoring programs)
- Patient's address is unable to be confirmed by the US Postal file when the patient is added to the computer system
- The prescriber or prescriber's handwriting is unfamiliar or different than typical (may have stolen a prescription blank)
- A prescription from a prescription pad it not "squared" having uneven edges and has no roughness or evidence of glue along the top (may have been printed on a PC and cut apart)
- A prescription from a prescription pad that has an unusual texture (could be photo copied or the original information could have been washed off with acetone)
- The prescription looks like it was photo-copied
- There are multiple handwritings or inks used (may have been altered)
- Non-standard abbreviations are used
- Illegal number of refills (may have been altered)
- Out of area/out of state prescriber
- Prescriptions for controlled substances from multiple prescribers
- Prescription profile showing only controlled substance medications and common "companion" prescriptions such as antibiotics
- Patient asks to only fill the controlled substance prescription and doesn't need any companion scripts
- Multiple controlled substance prescriptions being requested simultaneously
- Notes in the system such as "double count all controls" indicating the patient has reported being shorted previously
- Prescriptions for very large quantities of controlled medications
- Refills requested early

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

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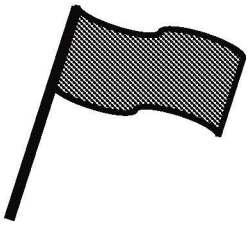
Fill

While Fill does not always have the easily retrieved computer access of some other stations, due diligence is still required. Due diligence is the responsibility of every Pharmacy Team Member If a technician or intern is unsure about the validity of a prescription, or questions if it is appropriate to fill, ALWAYS involve the appropriate pharmacist.

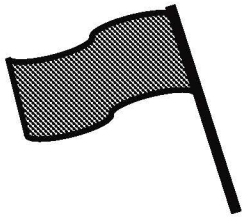
When counting/pouring a prescription, due diligence includes reviewing the hard copy of the prescription (if applicable), the quantity ordered and any notes from Data Entry.

Due diligence could include determining any/all of the following:

- Is the prescription from a local prescriber?
- Is all necessary information included on the prescription?
- Does the prescription look altered in any way?
- Is the prescription written for a dose within normal dosing range and a reasonable quantity?
- Are there any "red flags" or reasons to be suspicious of the prescription or quantity (see red flags list at the end of this section)



RED FLAGS FOR FILL



The following are suspicious behaviors or "clues" that additional due diligence may be necessary.

- The prescriber or prescriber's handwriting is unfamiliar or different than typical (may have stolen a prescription blank)
- A prescription from a prescription pad it not "squared" having uneven edges and has no roughness or evidence of glue along the top (may have been printed on a PC and cut apart)
- A prescription from a prescription pad that has an unusual texture (could be photo copied or the original information could have been washed off with acetone)
- The prescription looks like it was photo-copied
- There are multiple handwritings or inks used (may have been altered)
- Non-standard abbreviations are used
- Illegal number of refills (may have been altered)
- Out of area/out of state prescriber
- Multiple controlled substance prescriptions being requested simultaneously
- Patient asks to only fill the controlled substance prescription and doesn't need any companion scripts
- Notes in the system such as "double count all controls" indicating the patient has reported being shorted on previous controlled substance prescriptions
- Prescriptions for very large quantities of controlled medications

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

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Final Verification

While due diligence is the expectation of each Pharmacy Team Member, pharmacist are legally responsible for ensuring all reasonable verifications and precautions are complete before dispensing a controlled substance prescription. Consequently, the final responsibility of diligence rests with the pharmacist at Final Verification. Data entry can involve either a new or refill prescription.

New Prescriptions

When data entering a new prescription, due diligence includes determining if the prescription should be filled or if it will need to be verified by contacting the prescriber.

Due diligence could include determining any/all of the following:

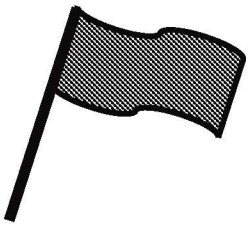
- Is the prescription for a regular patient?
- Does the patient receive medications other than controlled substance prescriptions and common "companion" prescriptions such as antibiotics
- Does the patient receive controlled substance prescriptions from multiple prescribers?
- Is the patient requesting an early fill of a controlled substance prescription?
- Is the prescription from a local prescriber?
- Is all necessary information included on the prescription?
- Does the prescription look altered in any way?
- Is the prescription written for a dose within normal dosing range and a reasonable quantity?
- Are there any DUR cautions that indicate the prescription is interacting with other controlled substances prescribed?
- Is the prescription dosage and quantity reasonable with consideration of the patient's age and disease states?
- Is the prescription billed to cash despite evidence of insurance coverage for the patient?
- Is the prescription filled with a DAW 2?
- Are there any "red flags" or reasons to be suspicious of the prescription (see red flags list at the end of this section)

Refill Prescriptions

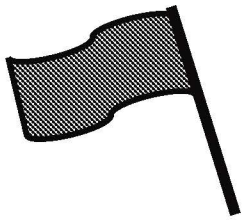
Due diligence is required when refilling prescriptions as well as when filling them for the first time. When a patient requests a refill, a major concern is determining if the medication is being used as intended.

Due diligence could include determining any/all of the following:

- Is the patient requesting an early refill of a controlled substance prescription?
- Did the prescription come from the "Refill Too Soon" queue/file?



Red Flags for Final Verification



The following are suspicious behaviors or "clues" that additional due diligence such as contacting the prescriber for verification may be necessary.

- Patient is new to the pharmacy (including Rx.com)
- The patient is not local (especially out of state to possibly avoid state prescription monitoring programs)
- Patient's address is unable to be confirmed by the US Postal file when the patient is added to the computer system
- The prescriber or prescriber's handwriting is unfamiliar or different than typical (may have stolen a prescription blank)
- A prescription from a prescription pad it not "squared" having uneven edges and has no roughness or evidence of glue along the top (may have been printed on a PC and cut apart)
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- Prescriptions for very large quantities of controlled medications
- Refills requested early

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

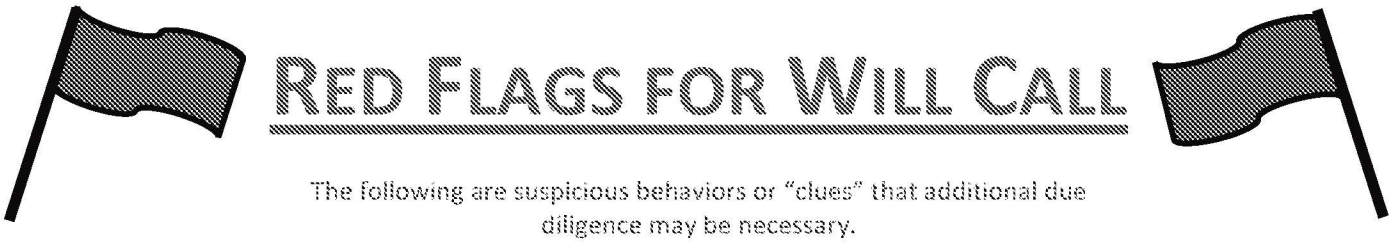
Giant Eagle Pharmacy Controlled Substances Manual

Will Call

While all necessary due diligence as to the validity of a prescription should be completed before the prescription is placed in Will Call, there are still patient behaviors can raise questions about the appropriateness of selling a controlled substance prescription. Due diligence is the responsibility of every Pharmacy Team Member If a technician or intern is unsure about selling a prescription, ALWAYS involve the appropriate pharmacist.

Due diligence could include determining any/all of the following:

- Does the customer request to only pick up the controlled prescription and not take any companion prescriptions?
- Does the customer offer to pay cash if there are any insurance issues?
- Are there any "red flags" or reasons to be suspicious of the customer's behavior (see red flags list at the end of this section)



The following are suspicious behaviors or "clues" that additional due diligence may be necessary.

- Patient appears nervous or over friendly
- Patient insists on waiting and "hovers" near the pharmacy
- The patient is not local (especially out of state to possibly avoid state prescription monitoring programs)
- Patient asks to only fill the controlled substance prescription and doesn't need any companion scripts

**The suggestions of due diligence on this and other pages in the manual are intended to provide examples but are not inclusive of all due diligence necessary in every situation. Each Pharmacy Team Member is expected to use professional judgment to determine necessary reasonable measures in each situation.

Giant Eagle Pharmacy Controlled Substances Manual

Verifying Controlled Substance Prescriptions

Once it has been identified that a controlled substance prescription requires additional validation, there are several recommendations to ensure you are able to correctly verify if the prescription is valid. These are not intended to be all inclusive and all pharmacists are expected to use appropriate judgment in each situation.

The first course of action is typically to call the prescriber to verify the prescription is legitimate and unaltered. Consider the following:

- The phone number on the prescription can be altered – when calling the prescriber, retrieve the phone number from an alternate source such as the prescriber file on the computer, phone book, etc.
- When speaking to the prescriber, verify ALL information on the prescription in case multiple items were altered (such as quantity dispensed and refills)
- Do not depend on the "DEA Number Formula" when verifying a prescriber – it is available on the internet; instead check the prescriber file (using the Rx.com national data base feature) in the computer or national registry

If it is suspected that a legitimate prescriber was "conned" into giving an inappropriate prescription, contact the prescriber and share the medication profile or other reasons you suspect fraud so the prescriber can make an informed decision.

If it is suspected a prescriber is willingly participating in writing fraudulent prescriptions, report the behavior to the DEA for investigation. Contact your PDL for guidance about dispensing prescriptions from the prescriber.

It is always advisable to utilize the state Prescription Monitoring Program when available. It can show prescriptions received by the patient from other pharmacies and may also allow evaluation of prescriber habits.

When trying to determine if a dosage or quantity of a controlled substance prescription is appropriate, consult the prescriber and/or patient inquiring about disease states and medication history.

Anytime a prescription is investigated, document the investigation and result on the prescription or image note. Include the date, name of the prescriber or prescriber's agent, investigation, results and pharmacist initials.

If a prescription if verified as fraudulent, it is preferred to void and keep the prescription in case it is needed for law investigation or other use. Our Team Member safety is our first concern, however, so pharmacist judgment should be used.

Giant Eagle Pharmacy Controlled Substances Manual

Ordering Controlled Substance Medications

Schedule III – Schedule V medications are ordered with all other pharmacy merchandise and the order can be completed by any qualified Pharmacy Team Member. Schedule II medications have specific ordering requirements and must be completed by a pharmacist.

DEA Form 222

Schedule II medications must be ordered using a DEA Form 222 or electronic equivalent. At this time, we use the paper version of the form.

Completing the DEA 222 Form

When a DEA Form 222 is received, the bottom portion of the form including the DEA number, name and address of the pharmacy, date the Form 222 was issued, the approved schedules the pharmacy can order and the form number is completed by the DEA and already on the forms. The following fields are completed by the pharmacist when ordering Schedule II medications (please refer to the example on the following page):

1. The name and address of the supplier
2. The date the order is written
3. The quantity of the medication ordered
4. The package size ordered
5. The medication name, strength and dosage form
6. The total number of lines completed on the form – this refers to the last "line number" completed on the form and does not correlate with the number of bottles of product ordered
7. The signature of pharmacist with power or attorney to sign the order form

The rest of the DEA Form 222 is left blank. Several fields are completed when the medication is received and they will be covered under the "Receiving Controlled Substances" section.

The completed form is faxed to the supplier. The bottom copy (blue) of the DEA is removed and retained at the pharmacy. The remaining copies are placed in an envelope provided by the supplier and given to the delivery driver. The medications will be delivered the next delivery date.

A DEA Form 222 will not be filled from the supplier if it is not complete and legible. No items may be altered, erased, or corrected. If an error is made when completing a DEA Form 222, the form must be voided and a new form completed. All voided forms must be kept in the pharmacy and available for inspection.

Giant Eagle Pharmacy Controlled Substances Manual

BLANK DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)* | STREET ADDRESS

CITY and STATE (1) | DATE (2) | TO BE FILLED IN BY SUPPLIER: SUPPLIER'S DEA REGISTRATION No.

LINE No.	TO BE FILLED IN BY PURCHASER: No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	(3)	(4)	(5)			
2						
3						
4						
5						
6						
7						
8						
9						
10						

(6) ◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)* | SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT (7)

Date Issued	DEA Registration No.	Name and Address of Registrant
Schedules		
Registered as a	No. of this Order Form	

DEA Form 222
(Oct. 1982)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

Giant Eagle Pharmacy Controlled Substances Manual

Power of Attorney to Sign an Official Order Form

Each pharmacist who orders Schedule II medications must have Power of Attorney to Sign an Official Order Form. The form is available on GE Central. It is expected that each pharmacist working in a pharmacy have the power of attorney along with any floaters working at the location when an order needs to be prepared.

One of the security recommendations to minimize theft risk and loss is to keep only the necessary inventory on hand. This requires frequent Schedule II orders to be completed. It is expected that the Pharmacy Leader and Staff Pharmacists will communicate with Floater Pharmacists about ordering needs and Floater Pharmacists will complete and sign the power of attorney form when necessary.

The signature of the pharmacist completing the power of attorney must be witnessed by two other individuals. They can be any Pharmacy or Store Team Members.

To complete the Power of Attorney for DEA Forms 222 and Electronic Orders Form (please refer to the example on the following page):

- Access GE Central
- Select the "View Pharmacy Library" link from the "Features" tab of the Pharmacy Library
- Select the "Compliance" folder
- Select the "Controlled Substance Compliance" folder
- Select the "Controlled Substance Power of Attorney" document
- Print the "Power of Attorney for DEA Forms 222 and Electronic Orders" (see example below)
- Complete the following fields:
    1. Name of registrant (Giant Eagle Pharmacy #XXXX)
    2. Address of registrant (Pharmacy address)
    3. DEA registration number (Pharmacy DEA number)
    4. Name (Pharmacist name)
    5. License Number (Pharmacist license number)
    6. Registered pharmacist name line (print the Pharmacist's name)
    7. Registered Pharmacist signature and date
    8. Witness 1 signature and date
    9. Witness 2 signature and date
- File the form in the Controlled Drug Box in the pharmacy

Power of Attorney for DEA Forms 222 and Electronic Orders

Name of registrant: 1

Address of registrant: 2

DEA registration number: 3

I, Anthony Mollica, the undersigned who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint:

Name: 4

License Number: 5

my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

Anthony Mollica, RPh.
Vice President, Pharmacy Operations
Giant Eagle, Inc.

I, 6 (registered pharmacist), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

Signature of attorney-in-fact/
Registered Pharmacist: 7 Date:

Witnesses: 1. 8 Date:

Witnesses: 2. 9 Date:

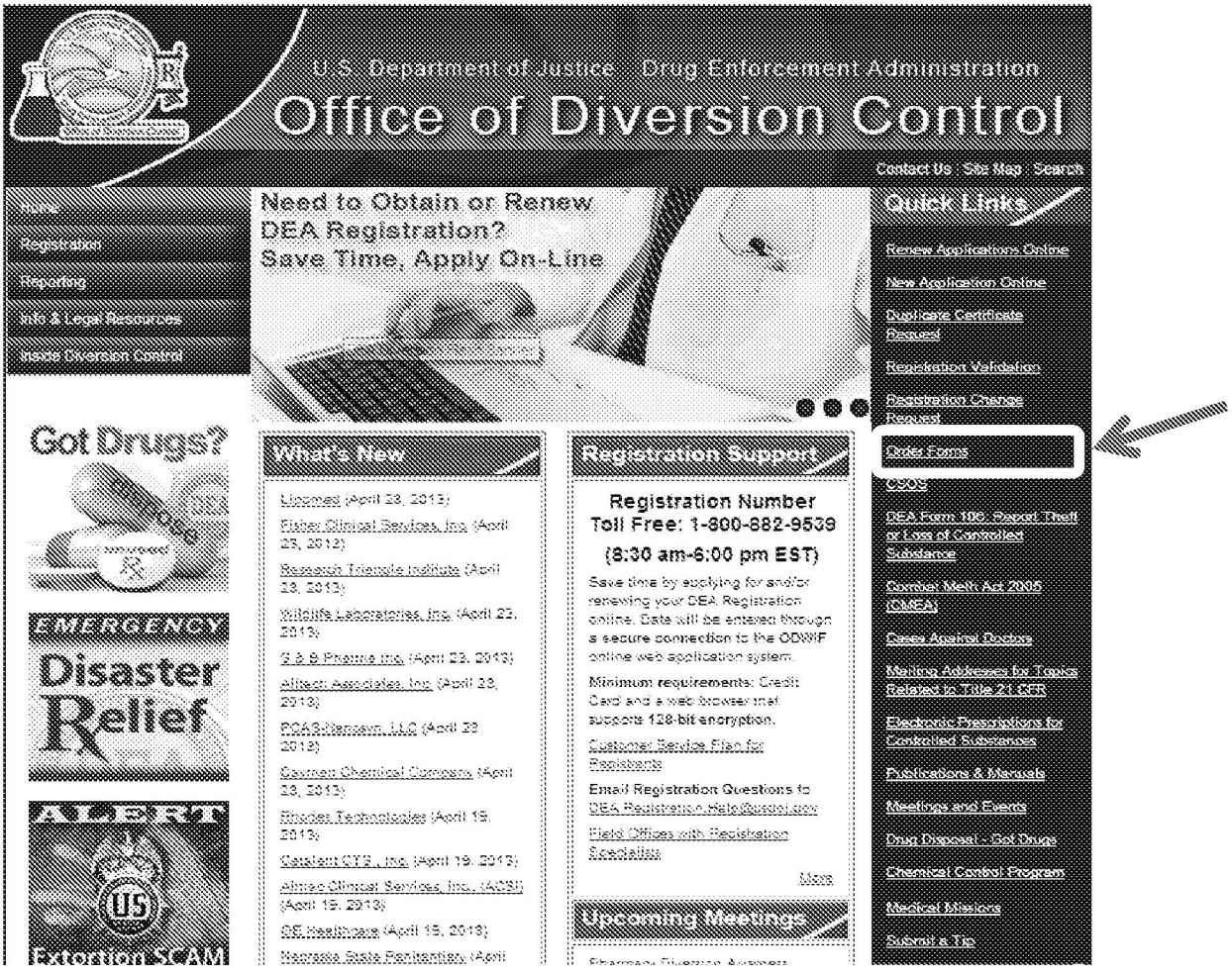
Giant Eagle Pharmacy Controlled Substances Manual

Ordering DEA Form 222 Order Forms

To reorder DEA Form 222 order forms:

- Access www.deadiversion.usdoj.gov
- Select "Order Forms"
- Complete the order form (see instructions on the following page)

Each book of DEA Form222 consists of seven sets of forms. Each pharmacy is typically provided with the maximum of six books per order. DEA Forms 222 can also be ordered by calling 1-800-882-9539 or by contacting the local DEA Registration Specialist.



Giant Eagle Pharmacy Controlled Substances Manual

To complete the Order Forms Request Screen:

1. Enter the DEA number of the pharmacy
2. Enter the Giant Eagle pharmacy name EXACTLY as it appears on the pharmacy registration form including any punctuation
3. Enter the pharmacy phone number
4. Select "Submit"

Order Forms Request Screen:

All requests for official order forms (DEA Form 222) can be made by registrants who are registered in Schedule I and/or II. Complete the form below in its entirety and click the Submit button.

1 **DEA Number*** (**Required** - Not Case Sensitive)

Last Name or Business Name* (**Required** - Not Case Sensitive)
As it appears on your registration. Example:
If "Smith, John Q MD" is on your registration, then enter: **Smith**
If "Smith's, Pharmacy" is on your registration, then enter: **Smith's**
If "Smith's Pharmacy" (no comma) is on your registration,
then enter: **Smith's Pharmacy**

2

Phone Number* (**Required so we may contact you if we cannot fulfill your request**)

3

4 Submit

You will receive the maximum number of order form books allowed for your business activity.

Giant Eagle Pharmacy Controlled Substances Manual

Receiving Controlled Substance Medications

Receiving Schedule III – V medications

Schedule III – V medications are included in the delivered totes from the wholesaler and are quarantined in white plastic bags. When the delivery is received:

- Escort the driver to the area in the pharmacy where the order is processed
- Verify the number of totes delivered matches the driver's delivery log and sign for order

A pharmacist must check in the controlled drugs when the totes are opened and the controlled substance bags are removed and placed in the designated area in the pharmacy. The controlled substances are NOT to reside in the designated area without being verified by a pharmacist and must be placed on the shelves as quickly as possible. To check in Schedule III – V medications, the pharmacist must:

- Circle the quantity on the shipping list/invoice and initial the corresponding line
- Sign (full signature) and date the invoice after verifying each item on the shipping list/invoice is correct
- File the invoice in chronological order in the appropriate tab of the Controlled Drug Box

Any discrepancies between the invoice and the received quantities must be immediately resolved by contacting the supplier.

Receiving Schedule II medications

Schedule II medications must be checked in and verified with all the requirements of Schedule III – V medications along with completing the DEA Form 222. Schedule II mediations are to be checked in immediately upon opening the tote and placed in the safe as soon as they are verified. Only a pharmacist may check in and verify Schedule II medications. To check in Schedule II medications:

- Circle the quantity on the shipping list/invoice and initial the corresponding line
- Sign (full signature) and date the invoice after verifying each item is correct
- Complete the remaining required fields of the DEA Form 222 (please refer to example in the following page)
    1. Enter the NDC number received
    2. Enter the number of packages received
    3. Enter the date received
- Place the Schedule II medications in the safe
- Staple the completed DEA Form 222 to the corresponding signed and dated invoice
- Update the received medications on the perpetual log if applicable
- Apply the order (RapidFill) or update on-hand counts (PDX)
- File the invoice in chronological order in the appropriate tab of the Controlled Drug Box

Giant Eagle Pharmacy Controlled Substances Manual

BLANK DEA FORM-222
U.S. OFFICIAL ORDER FORM - SCHEDULES I & II

See Reverse of PURCHASER'S Copy of Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010
TO: *(Name of Supplier)*	STREET ADDRESS	
CITY and STATE	DATE	TO BE FILLED IN BY SUPPLIER SUPPLIER'S DEA REGISTRATION No.

LINE No.	TO BE FILLED IN BY PURCHASER No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1				1	2	3
2						
3						
4						
5						
6						
7						
8						
9						
10						

LAST LINE COMPLETED *(MUST BE 10 OR LESS)*	SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT	
Date Issued	DEA Registration No.	Name and Address of Registrant
Schedules		
Registered as a	No. of this Order Form	

DEA Form 222
(Oct. 1982)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II
DRUG ENFORCEMENT ADMINISTRATION
SUPPLIER'S Copy 1

Note: The graphic illustrated above is only a depiction of the DEA Form-222. It is not intended to be used as an actual order form.

Giant Eagle Pharmacy Controlled Substances Manual

Returning Controlled Substance Medications

There are two common situations when a controlled substance medication is returned:

- Product is removed from inventory due to expiration date
- Product is returned to the supplier due to an ordering issue

In either situation, the product must be separated from normal inventory and secured. All controlled substance medications removed from active inventory (Schedule II – V) must be stored in a locked cabinet until the product is placed in a container and sealed (outdate returns) or given returned to the supplier (ordering issues).

When returning outdated product, the following steps are completed:

- The product is identified as expiring within 90 days and removed from active inventory and given to the pharmacist – the remaining steps must all be completed by a pharmacist
- The product is counted and the total quantity is written on the container
- The on-hand count is updated to reflect the removed inventory
- The product is placed in the locked storage cabinet
- When the quarterly inventory return is being processed, the pharmacist completes the necessary scanning/documentation to return the outdated controlled products
- The outdated controls are placed in a plastic bag following the outdate company return procedures
- The bag is placed in a vial box when it is ready to be sealed and the box is sealed immediately

When returning a product to the supplier, the following steps are completed:

- The product is identified as needing to be returned due to received damaged, overage or other ordering issue
- The supplier is contacted and return procedures completed
- If necessary, the pharmacist updates the on-hand count to reflect any removed inventory
- The pharmacist places the product in the locked storage cabinet
- When the return authorization is received the pharmacist places the product in a prescription bag or other sealed container and gives the product to the delivery driver for return

Giant Eagle Pharmacy Controlled Substances Manual

Auditing Controlled Substance Medications

Since we stock controlled substances medications with a high abuse potential, we have a responsibility to regularly audit our inventory to identify any diversion. Giant Eagle requires monthly auditing on all Schedule II medications and all Hydrocodone and Suboxone containing products. In addition, every year on May 1st, there is an annual audit (inventory) of all controlled substance medications.

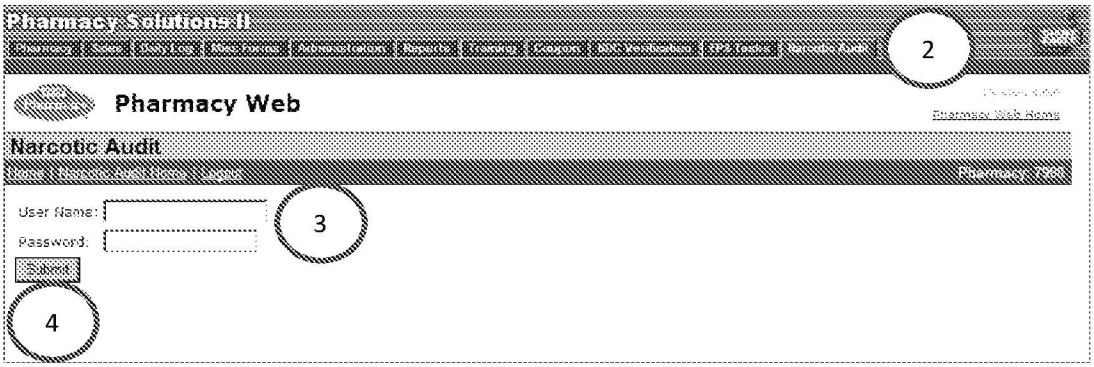
Monthly Narcotic Audit

Each month every Schedule II medication and Hydrocodone containing medication must be inventoried by exact count and recorded in the Monthly Audit Program. It is to be completed by the 15th of each month.

Logging onto the Narcotic Audit Program

Every pharmacist has access to the Monthly Audit Program. The program uses the same user code and password used by pharmacy software. The first time a pharmacist is set up in the Monthly Audit Program, the user code and password from the software database is entered. In RapidFill, the password can be updated by entering a service ticket with Pharmacy Support. In PDX Legacy, the password will update automatically when it is changed in the PDX Legacy program. To log onto the Narcotic Audit Program (please refer to example below):

1. Log onto Pharmacy Solutions
2. Select the "Narcotic Audit" tab
3. Enter the user name (RXPXXX) and password of the pharmacist completing the monthly audit
4. Select "Submit"



Giant Eagle Pharmacy Controlled Substances Manual

Creating a Baseline Audit

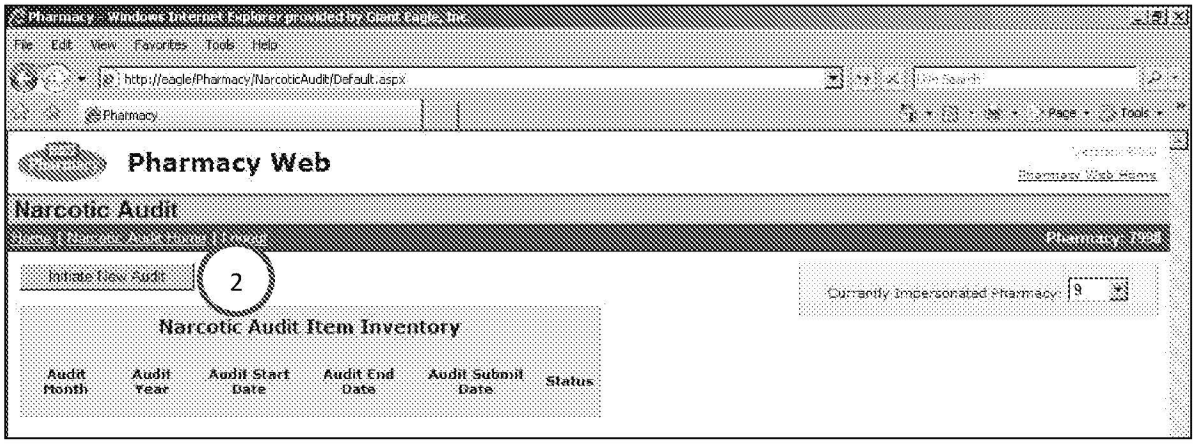
The first time a pharmacy uses the Monthly Narcotic Audit program, a baseline audit must be completed to populate the initial on-hand counts. Once the baseline audit is complete, the previous month's on-hand counts will be used to create the starting count of the following month. For the procedure to create a baseline audit, please see the "Standards" folder on GE Central.

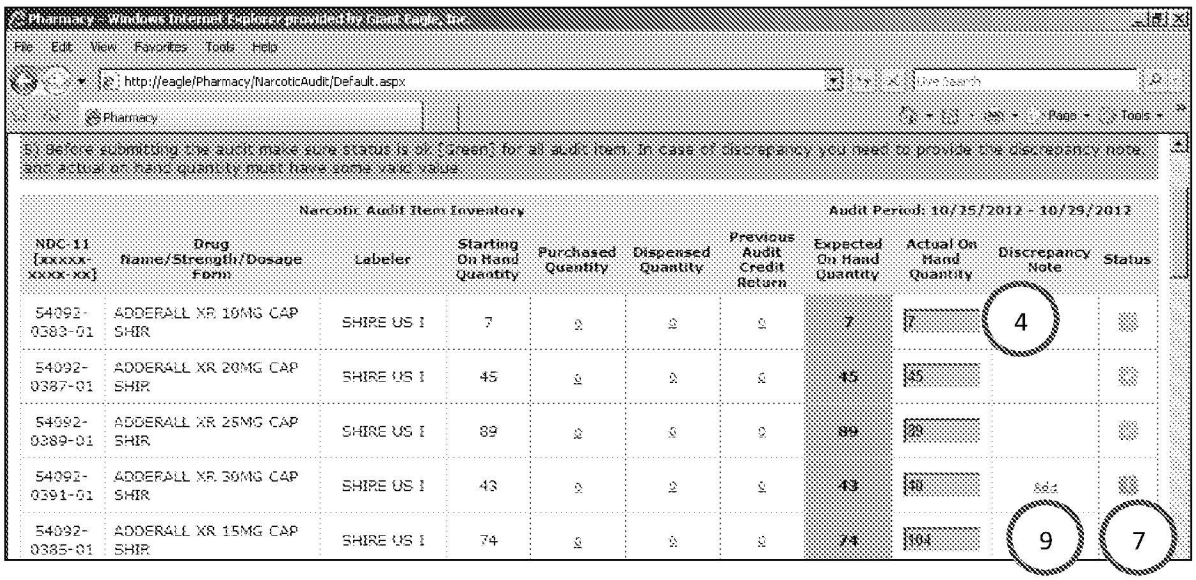
Completing the Monthly Narcotic Audit

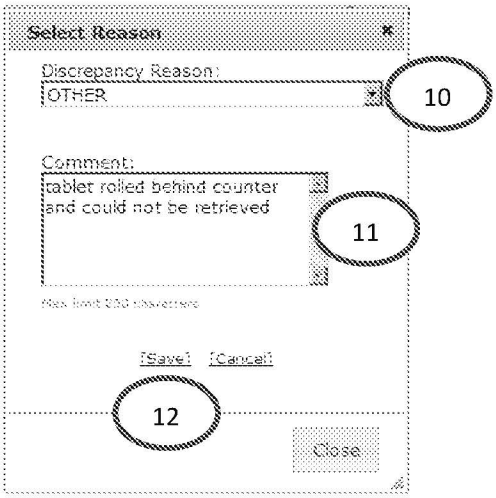
The monthly audit is based on the information provided on the day BEFORE the audit is completed. To ensure all data is accurate, the Monthly Narcotic Audit Program MUST be initiated after 7am of the date of the audit. All physical counts MUST be completed before the start of business of the date of the audit. This is to prevent any confusion by receiving orders and dispensing prescriptions not included in the audit. Physical counts can be completed at the close of business the day before the audit or before the opening of business the day of the audit. Once the audit is completed and submitted, it cannot be edited. If changes need to be made, they must be written on the printed copy of the audit and resolved electronically the following month. To complete the Monthly Narcotic Audit (please refer to examples on the following page):

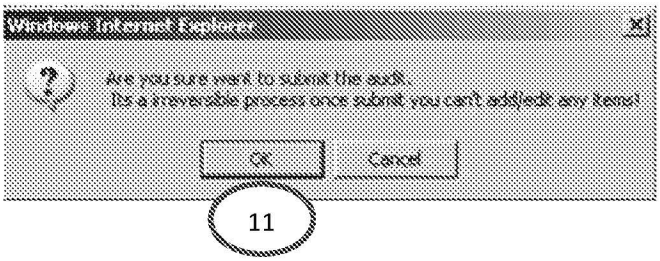
1. Log onto the Narcotic Audit Program using Pharmacy Solutions
2. Select the "Initiate New Audit" button
3. Select the first product listed on the Narcotic Audit Program
4. Enter the actual on-hand count (AOH)
5. Repeat for each product listed – all on-hand counts are to be entered before investigating any discrepancies
6. Verify all products in stock are included on the audit adding any new products if necessary (see "Adding New Products later in this section)
7. Identify any discrepancies between the expected on-hand count (EOH) and the actual on-hand count designated by an orange [!] in the "Status" field
8. Research the cause of the discrepancy (see "Resolving Monthly Audit Discrepancies" later in this section)
9. Select the "Add" link in the "Discrepancy Note" field
10. Select the discrepancy reason from the drop down menu
11. Enter a note explaining the discrepancy reason(s) in the "Comment" field
12. Select "Save"
13. Verify the reason and comments were successfully recorded designated by a green checkmark in the "Status" field
14. Repeat until all discrepancies are resolved and recorded
15. Select the "Submit Audit" button
16. Select the "OK" button
17. Print a copy of the audit the following day (a formatted final copy will be emailed to the pharmacy the day after the audit is submitted)
18. File the printed copy of the audit in the correct tab of the Controlled Drug Box

Giant Eagle Pharmacy Controlled Substances Manual









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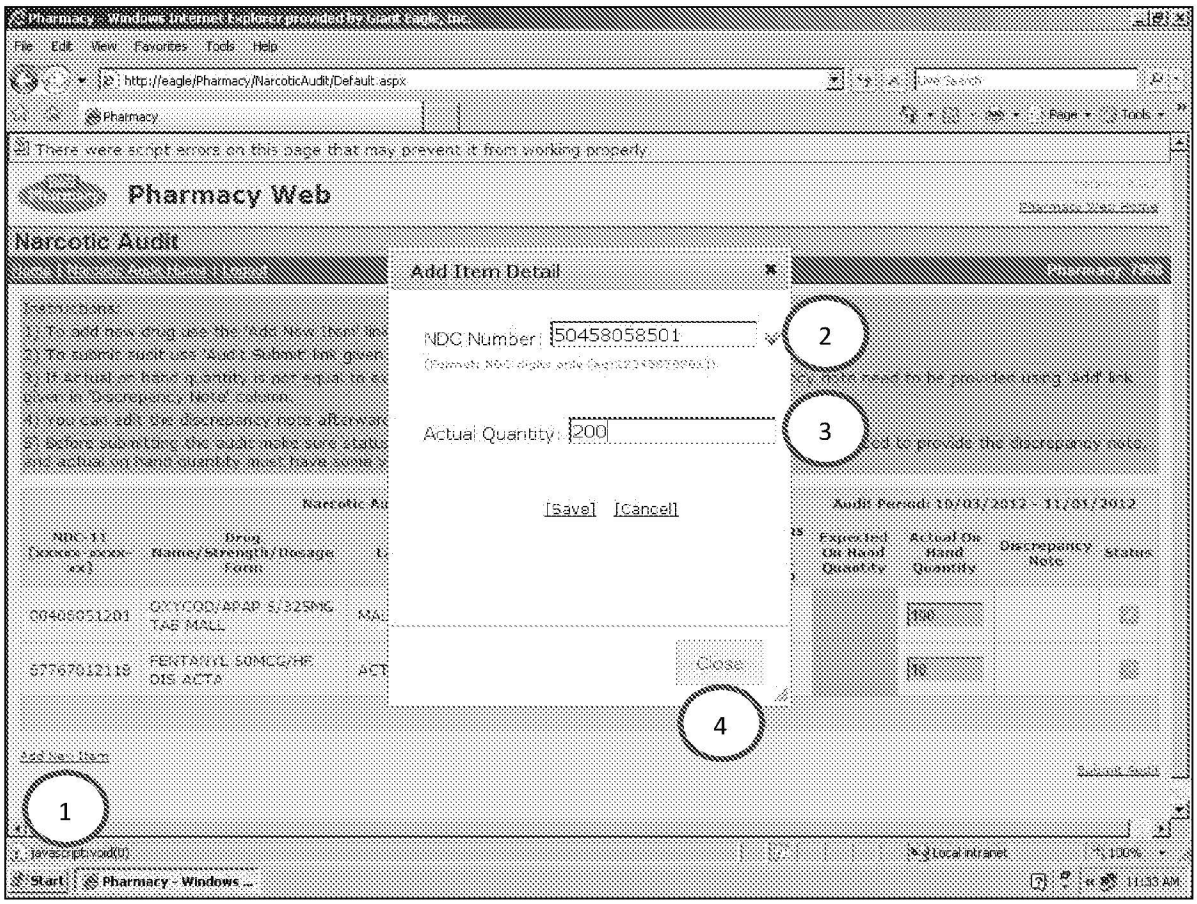
Adding Medications to the Monthly Narcotic Audit

Typically, the Monthly Narcotic Audit Program will automatically add all applicable medications ordered. Each NDC will have a separate entry so it may be required to have multiple entries for the same product if different manufacturers are in stock. If a product needs to be manually added to the narcotic audit (please see example below):

1. Select the "Add New Item" link at the end of the entries on the audit
2. Enter the NDC number of the medication to be added
3. Enter the actual on-hand quantity
4. Select "Save"

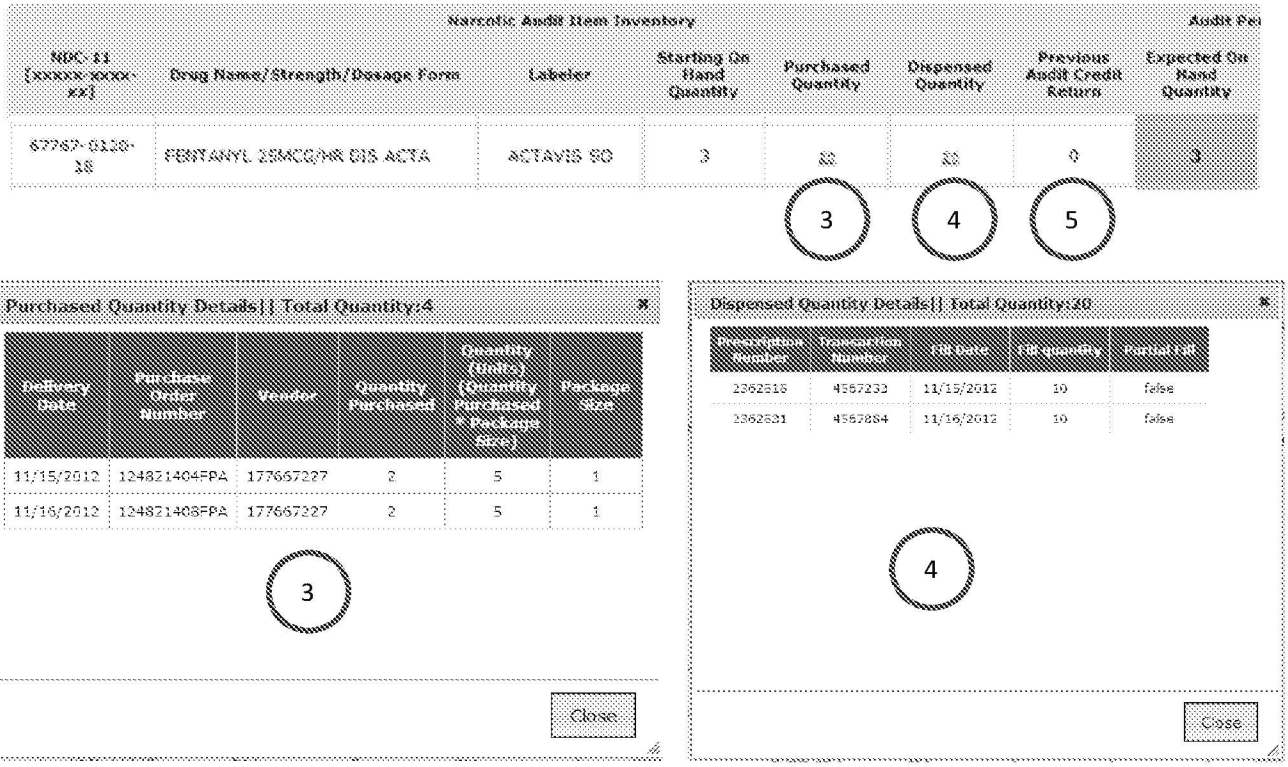


Giant Eagle Pharmacy Controlled Substances Manual

Resolving Monthly Narcotic Audit Discrepancies

Resolving discrepancies between the expected on-hand and the actual on-hand counts will require individual investigation. Suggestions to find common causes for discrepancies include:

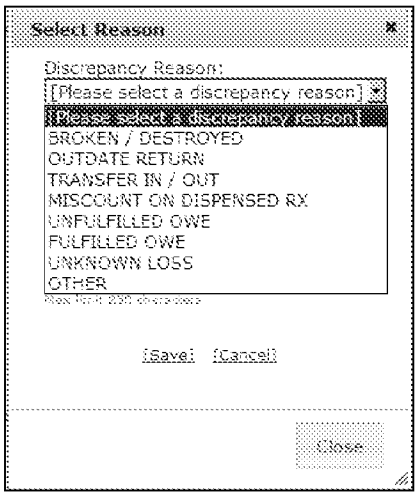
1. Verify the current day's deliveries are not included in the physical on-hand count (all information is based on the previous day's numbers)
2. Verify all outdates and broken pills are included on the physical on-hand count
3. Verify all received orders are included on the expected on-hand count by selecting the "Purchase Quantity" link and compare the information with invoices (see example below)
4. Verify all prescriptions dispensed are included on the expected on-hand count by selecting the "Dispensed Quantity" link and compare with prescriptions dispensed (see example below)
5. Verify all prescriptions returned to inventory from Will Call are included on the expected on-hand count by selecting the "Previous Audit Credit" link and compare to the "Return to Stock" report



Giant Eagle Pharmacy Controlled Substances Manual

Every discrepancy must include a selection of a reason from the "Discrepancy Reason" drop down menu and additional clarify information in the "Comment" field. The choices and when to use each reason include:

Broken/Destroyed



When a broken tablet or capsule is identified during the filling process, it is removed from active inventory, labeled with the medication name and NDC number and locked in the secure cabinet with outdates. It is still counted as part of the inventory on the monthly audit until it is returned with outdated medications (see Outdated/Returned below).

The Broken/Destroyed discrepancy reason is chosen if a medication is unable to be removed from inventory for later return. Examples include a crushed tablet or capsule and spilled liquids. Required supporting information in the "Comments" field includes why the medication was not able to be returned such as "tablet fell on the floor and was stepped on by a Team Member". Additional documentation may be required if the quantity is unusually large.

Outdated/Returned

The Outdated/Returned discrepancy reason is selected only AFTER the medication is removed from the pharmacy either via the designated outdate returns or to the supplier. Returned medications will cause a discrepancy the month FOLLOWING the medication's return. Required supporting information in the "Comments" field includes the date, quantity and reference number of the return.

Transfer In/Out

Due to regular six day a week deliveries and the additional requirements to transfer controlled substances, Giant Eagle does not encourage transfer controlled substance medications. If a medication is transferred in or out, required supporting information in the "Comments" field includes the amount transferred, date and transfer form number.

Miscount on Dispensed Rx

The intent of "Miscount on Dispensed Rx" discrepancy reason is to report KNOWN miscounts. Examples would include discovering a miscount using a perpetual inventory after the prescription is dispensed or a patient calling to complain of being shorted, confirming the short, but the balance is not picked up when the audit is completed. Required supporting information in the "Comments" field includes the prescription number, date and amount miscounted.

Giant Eagle Pharmacy Controlled Substances Manual

Unfulfilled Owe

The actual on-hand count must always be the amount of medication physically in the pharmacy. If a medication is owed, the expected on-hand count will be a negative number. The system will not accept a negative value in the actual on-hand count since you cannot have fewer than zero quantity in the pharmacy. When there is an outstanding medication owe when completing the audit, the discrepancy reason selected is "Unfulfilled Owe". Required supporting information in the "Comments" field includes the prescription number, date owed and amount owed.

Fulfilled Owe

If there was a discrepancy due to an unfulfilled owe the previous month, there will be a discrepancy the following month that is recorded as a "Fulfilled Owe". For example, if 30 tablets of a medication are owed one month, the narcotic audit that month will show an expected on-hand count as -30 and the actual on-hand count as zero. The audit will show that the pharmacy was over by 30 tablets with a discrepancy reason of "Unfulfilled Owe". The following month, the expected on-hand count will be based on a starting quantity of -30, but the actual on-hand count will be based on a starting quantity of zero. The audit will show the pharmacy is short by 30 tablets with a discrepancy reason of "Fulfilled Owe". Required supporting information in the "Comments" field includes the prescription number, date owed and amount owed.

Unknown Loss

If it is not possible to determine the reason for a shortage, the "Unknown Loss" discrepancy reason is selected. This reason should only be chosen after all possible investigation has been completed. If it is not possible to resolve a discrepancy before the end of the day of the audit, it may be left open for an additional day to allow time for further research. Required supporting information in the "Comments" field could include assumed miscount or still under investigation.

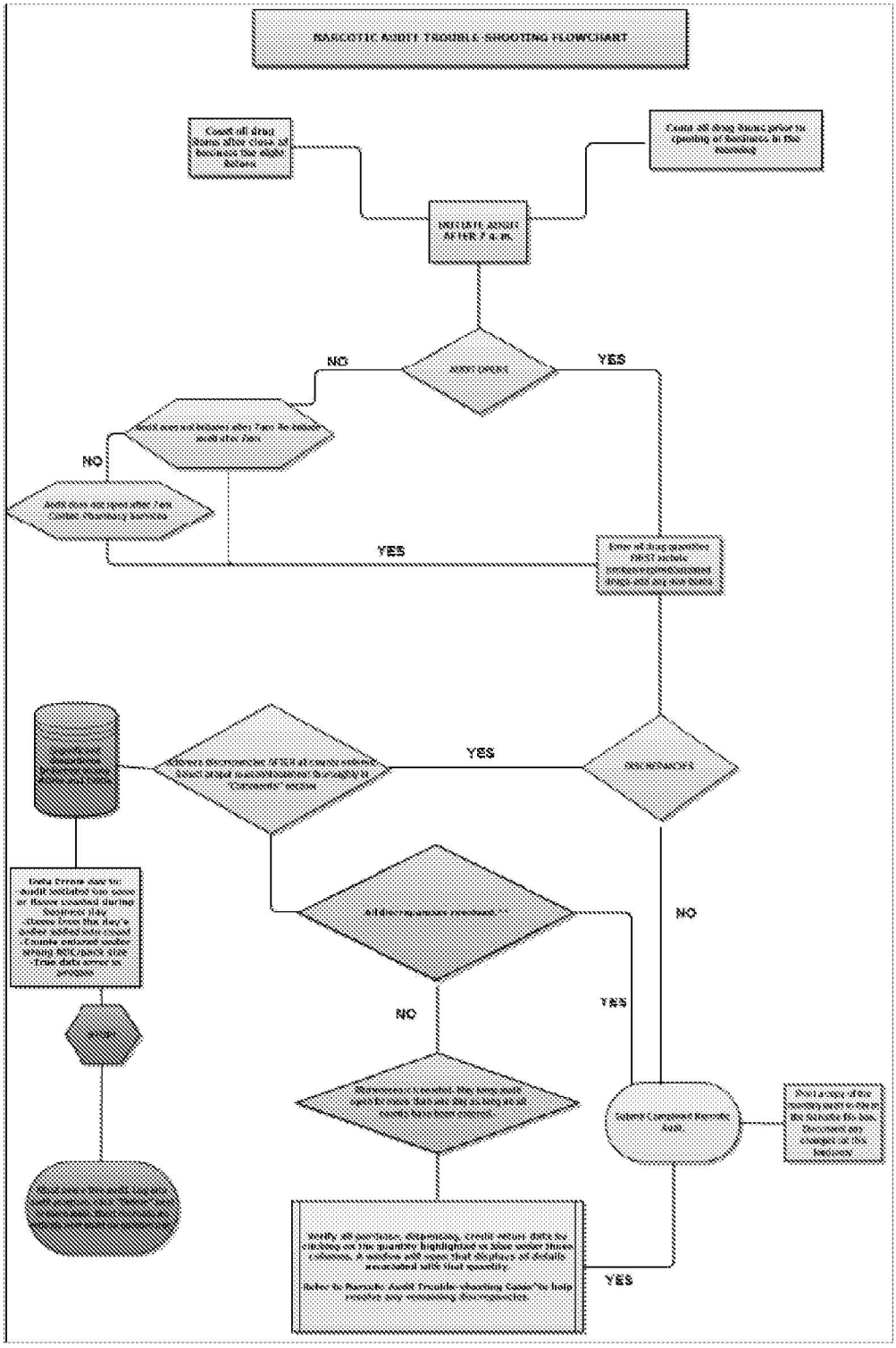
Other

The "Other" discrepancy reason is used when there is a known reason for the discrepancy that is not covered under the other categories. One example could include if an NDC number was changed and the pharmacy only had the old NDC number in stock. Since each NDC number is a separate line on the audit, there would include two lines for the product, one for each NDC number. The old NDC number would show as a shortage (was dispensed, but not billed) while the new NDC number was show as an overage (was billed, but not dispensed). Required supporting information in the "Comments" field would include the specific reasons and any supporting documentation (such as the prescription number and date in the example above).

Giant Eagle Pharmacy Controlled Substances Manual

Monthly Audit Flowchart

As a helpful reference, the steps to complete the monthly audit are listed in flowchart format below.



Giant Eagle Pharmacy Controlled Substances Manual

Annual Controlled Substance Inventory

The Controlled Substance Act requires every pharmacy complete a biennial inventory of all controlled substances in stock. The inventory must be completed before the opening or after the closing business on May 1st. Giant Eagle requires the inventory to be completed on an annual basis. The purpose of completing the inventory annually is to create a single starting date to investigate suspected loss or theft of controlled substances.

The inventory requirements include:

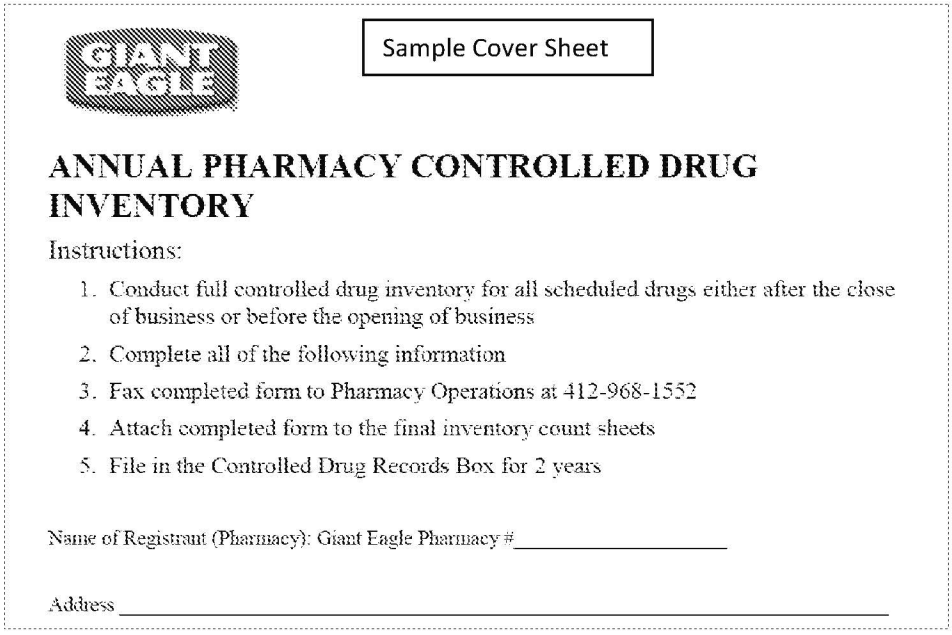
- Record of the name, address and DEA number of the pharmacy
- Record of the date and time the inventory was completed (opening or closing)
- Signature of the person(s) responsible for completing the inventory
- The inventory must be maintained at the location and be available for inspection for at least two years
- Schedule II medication inventory records must be separate from all other controlled substances
- All Schedule II medications must have an exact count recorded
- Schedule III – V medications may use an estimated count
    - If the container holds more than 1000 units and has been opened, an exact count must be recorded

To access the documents on GE Central:

- Select the "View Pharmacy Library" link in the pharmacy dashboard on GE Central
- Select the "Compliance" folder
- Select the "Annual Inventory" folder

Documents are stored on GE Central to assist in the inventory including:

- Cover sheet for the inventory (see example below)
- List of all Schedule II medications in the computer drug database
- Instructions to run a report listing all Schedule III – V medications with on-hand counts in the computer



GIANT EAGLE

Sample Cover Sheet

ANNUAL PHARMACY CONTROLLED DRUG INVENTORY

Instructions:

1. Conduct full controlled drug inventory for all scheduled drugs either after the close of business or before the opening of business
2. Complete all of the following information
3. Fax completed form to Pharmacy Operations at 412-968-1552
4. Attach completed form to the final inventory count sheets
5. File in the Controlled Drug Records Box for 2 years

Name of Registrant (Pharmacy): Giant Eagle Pharmacy #_____

Address _____

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Completing the Annual Controlled Substance Inventory – Schedule II Medications

The most efficient method of completing the Schedule II portion of the Annual Controlled Substance Inventory is to complete the May Monthly Narcotic Inventory concurrently. After completing the May Monthly Narcotic Inventory, print two copies of the report. One copy is filed with the Monthly Narcotic Audits in the Control Drug Box, the second copy is stapled to the cover sheet and the Schedule III – V Annual Inventory Report and filed in the Annual Inventory tab of the Control Drug Box.

If it is not possible to complete the May Monthly Narcotic Inventory concurrently, the Schedule II portion of the Annual Controlled Substance Inventory must be completed separately.

1. Access the CII List for Annual Inventory on GE Central
2. Print or save the file to the pharmacy desktop
3. Enter the EXACT on-hand count of every Schedule II medication in stock
4. Attach the file to the cover sheet and the Schedule III – V Annual Inventory Report
5. File in the Annual Inventory tab in the Control Drug Box
6. Complete the May Monthly Narcotic Audit as usual before the deadline

Completing the Annual Controlled Substance Inventory – Schedule III – V Medications

Since all Schedule III – V medications in stock should have an associated on-hand count in the computer, a report can be run to list each controlled medication in stock. To complete the Schedule III – V medications inventory for the Annual Controlled Substance Inventory:

1. Select the "Tools" tab
2. Select "Reports"
3. Select "GE_Biennualinventory"
4. Select a printer from the "Printer" dropdown Menu
5. Select the "Run" button (see screenshot on the following page)
6. Verify the on-hand quantity on the report vs. the quantity on the shelf
7. Verify all Schedule III – V medications in stock are included on the report
8. Update/add any necessary on-hand counts in the computer
9. Re-run the report
10. Sign and date the report
11. Attach the report to the cover sheet and Schedule II Annual Inventory Report
12. File in the Annual Inventory tab in the Control Drug Box

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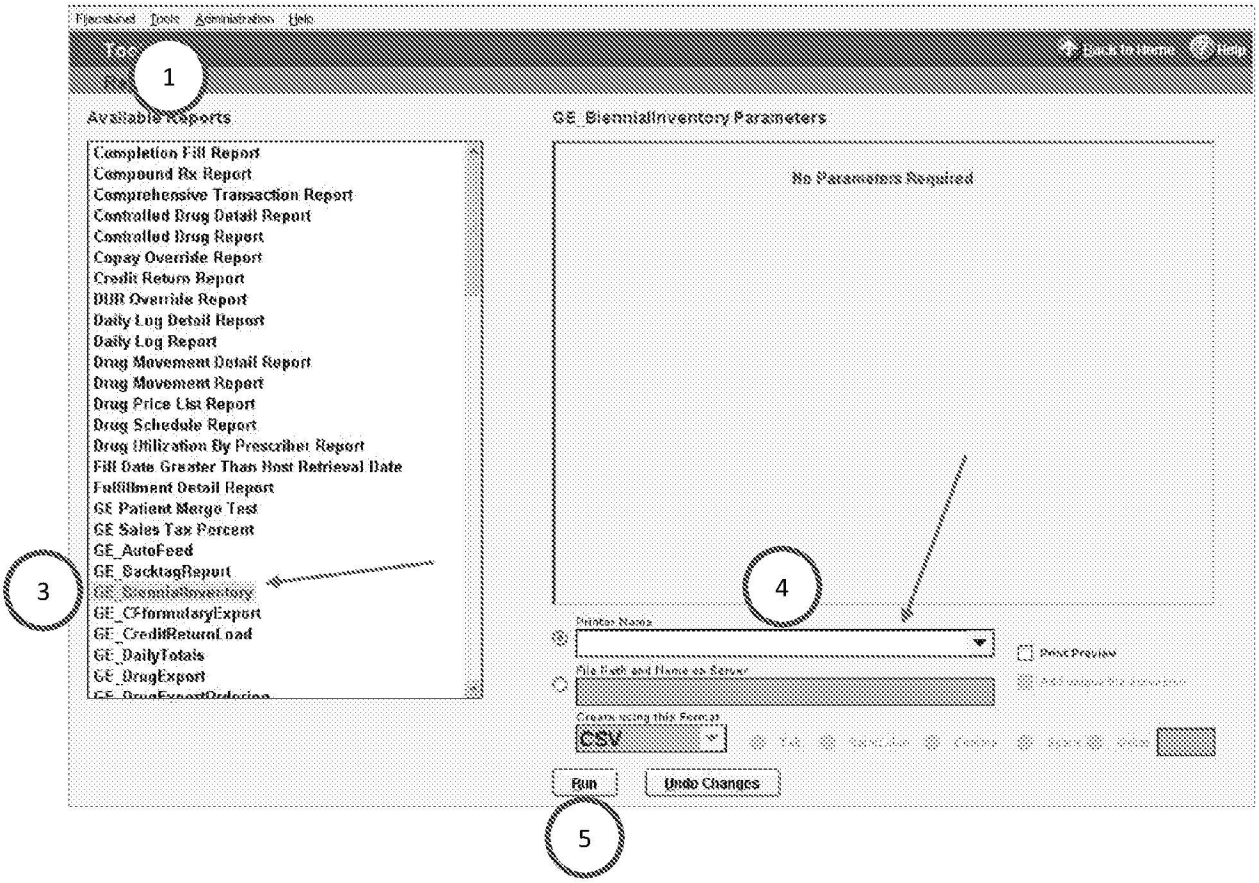

Sample Schedule III – V Report

Biennial Inventory Report 4/29/2009
GIANT EAGLE TEST SITE #6
101 KAPPA DR.
PITTSBURG, OH 15238
DEA#: GE0896362 Phone: (412) 963-6200

Schedule	NDC	Drug Name	On Hand
3	00093-3015-01	Apap/Codein 300/30 Tab Teva	385
3	00093-3035-01	Apap/Codein 300/60 Tab Lemm	100
3	63304-4056-10	Apap/Codeine 300-30 Tab Ranb	1,240
3	00406-6048-05	Apap/Codeine 300-60 Tab Mall	500
3	00143-3300-01	But/Apap/Caf Codein Cap West	130
3	00143-3178-01	Butal/Asa/Caff Tab West	240
3	68453-2014-16	Codimal Dh Syp Vict	16
3	00677-7160-33	Guai/P-Eph/H Syp Url	1
3	58177-7087-07	Histinex Hc Syr Ethe	480

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Schedule II Perpetual Inventory

While it is not required by policy, it is strongly recommended that all Schedule II medications are continuously audited using a perpetual inventory. Each time a Schedule II medication is received or dispensed, it is recorded using a perpetual inventory form. Perpetual Inventories offer the best security as the on-hand count is continuously monitored and they allow for immediate identification of any miscounts or diversion. The example below is available as an excel spreadsheet on GE Central using the following pathway:

- Select "View Pharmacy Library"
- Select the "Compliance" Folder
- Select "Schedule II Perpetual Inventory Form"

Schedule II Perpetual Inventory Form

Drug Name and Strength_____

Dosage Form_____ **Starting On-Hand Count**_____

Date	Time	Rx/Invoice Number	Qty Received/ Dispensed	Calculated Inventory	On-hand Count	Inventory Plus or Minus	RPh Initials

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Security of Controlled Substance Medications

With the growing illicit use of prescription controlled substance medications, there is also an increasing demand and "street value" for many of the medications we dispense. To prevent theft or diversion of our medications, we have required security procedures. Security requirements include procedures in all the following situations:

- Filling controlled substances prescriptions
- Receiving controlled substances
- Storing controlled substances
- Auditing controlled substances
- Inventorying controlled substances (physical inventory)
- Personnel security procedures

Team Member Assistance

Giant Eagle does everything possible to verify the background of each Team Member. We respect all Team Members and believe our Team Member typically act with honesty and integrity. Unfortunately, drug abuse is a national problem and not all of our Team Members are immune. Giant Eagle is also accountable as a company for implementing security procedures to limit and identify theft or other misuse of controlled substances. If you have a problem with addiction, we want to support every effort to help you. Please contact our Life Resources Assistance Program at 855-343-5433 for company sponsored assistance in overcoming addiction or other life challenges.

General Security Procedures

The goal of the controlled substance security procedures is to discourage and identify theft while protecting innocent Team Members from undo suspicion or accusations. General security procedures include:

- Regular rotation of duties – the same Team Member should not always put the order away, complete the monthly audit, review the shelves for outdates, etc.
- Prompt placement/return of all controlled medications to stock – controlled medications should be left sitting on a counter or otherwise unsecured or in a private area of the pharmacy
- Secure all controlled substance medications when removed from inventory
- Limit controlled substance inventories to minimum necessary – this includes reviewing which controlled substance medications need to be ordered in bulk containers
- Limit personal items in the pharmacy
- Limit people in the pharmacy to only those scheduled to work and necessary auxiliary Team Members such as PDLs, Store Leaders, Trainers, etc.

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Filling Controlled Substance Prescriptions

To verify accuracy and security of controlled substances, the following security procedures must be followed during the filling process:

- All Schedule III – V medications must be double counted (may be the same Team Member)
  - A double "X" (XX) and the initials of the Team Member who completed the second count are placed on the upper right hand corner of the prescription label
- All Schedule II medications are stored in a locked cabinet and accessible only to pharmacists (pharmacists must retrieve and return all Schedule II medications)
- Schedule II medications must be double counted by two different Team Members
  - The second count must be completed by a pharmacist
  - A double "X" (XX) and the initials of the Team Member who completed the second count are placed on the upper right hand corner of the prescription label

Receiving Controlled Substance Prescriptions

Receiving medication deliveries requires the entry of a non-pharmacy Team Member (delivery driver) and risks controlled substances being left in a non-approved area. To ensure proper security:

- Delivery drivers may enter the pharmacy, but must be escorted and accompanied by a Pharmacy Team Member at all times
- Controlled substance medications received must be checked in when the totes are opened
- After the controlled substance medications are checked in, they must be put away promptly
  - Schedule II medications must be put away by the pharmacist IMMEDIATELY after being checked in

Storing Controlled Substances

Security procedures for storage of controlled substances focus on limiting access to authorized Team Members and proper dispersal on non-secured controlled substance medications.

- All Schedule II medications are stored in locked cabinets
- All controlled substances removed from inventory are stored in locked cabinets
- Only pharmacists have access to locked cabinets and the key is on their person at all times
- Controlled substances not secured must be dispersed throughout the pharmacy inventory
  - It is acceptable to include controlled substances in the "fast mover" area
- Controlled substances are not left "staged" on counters, in boxes, etc.
- The pharmacy must be secured with gates and/or door locks and activated alarms when the pharmacy is closed and a pharmacist is not present in the building

Auditing Controlled Substances

Regular auditing of controlled substances is the best way to identify any theft or other possible problem with the controlled substance inventories.

- The Monthly Narcotic Audit is completed every month by a pharmacist
- The pharmacist that completes the Monthly Narcotic Audit is rotated regularly
- Discrepancies are researched and reported immediately

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Inventorying Controlled Substances (Physical Inventory)

Several times a year, the pharmacy is inventoried using an outside inventory company.

- A pharmacist is scheduled to assist the inventory team
  - The inventory pharmacist has no production requirements during the inventory
- The inventory pharmacist must directly oversee the inventory team member completing the inventory of the secured cabinets
- The inventory pharmacist must total the Will Call prescriptions and provide the total to the inventory team
- The inventory team is never left alone in the pharmacy

Personnel Security Procedures

As part of the necessary security procedures to deter theft of controlled substances, Giant Eagle has required personnel security procedures including:

- No unauthorized people are not allowed in the pharmacy at any time including:
  - Salespeople
  - Customers
  - Family and/or friends
  - Off-duty Team Members (other than salaried registered pharmacists)
- Authorized personnel may only be in the pharmacy when a pharmacist is on duty including:
  - Schedule Pharmacy Team Members
  - Store Leadership
  - Visiting Leadership (including internal auditing personnel)
  - Pharmacy trainer and audit Team Members
  - Pharmacy delivery drivers (must be escorted at all times)
  - Law enforcement officials and State Board of Pharmacy inspectors (must show credentials before admittance)
  - Maintenance/repair persons (must show credentials before admittance)
  - Third party auditors (must show credentials before admittance)
- Pharmacists may not fill prescriptions for themselves or family members
  - If not other pharmacist is on duty, store leadership may witness the filling and dispensing of the prescription; the witnessing leader must initial both the hard copy of the prescription and the signature log/signature capture pad
- Team Members may not ring up prescriptions or purchases for themselves or family members
- Personal items such as purses, coats and bags must be stored outside the pharmacy in designated lockers (on-going efforts are underway to provide lockers in all stores)
  - Small personal items may be brought in a clear, plastic bag and stored in a designated area in the pharmacy
- Cellphones must be silenced and stores in a designated area in the pharmacy
  - Cellphones may only be checked during breaks and before and after shift
- Smocks are not to be worn in the store and must be removed before leaving the pharmacy for break
- Smocks and bags checks will be instituted when necessary

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Suspected Theft or Loss of Controlled Substances

If there is a confirmed theft of controlled substances or unexplained significant shortage (suspected theft), the loss MUST be reported and investigated as quickly as possible. To access all required forms when reporting, tracking and investigating a controlled substance loss:

- Select the "View Pharmacy Library" link from the Pharmacy Dashboard in GE Central
- Select the "Compliance" folder
- Select the "Controlled Substance Compliance" folder
- Select the required form

Reporting Suspected Controlled Substance Loss

For both investigational and legal reasons, a significant loss or theft of controlled substances must be reported starting the day of the loss or the date the loss is discovered. The required reporting and maximum time allotted for each task are as follows:

- The date of the suspected loss (or date the suspected loss is discovered)
  - Pharmacy Team Leader notifies the PDL and Senior Manager, pharmacy Quality and Compliance (SMPQ&C)
  - PDL collects relevant documentation
  - SMPQ&C contacts Loss Prevention (LP), Risk/Legal and Pharmacy Leadership
- Within one business day of the suspected loss
  - Pharmacy Team Leader completes Controlled Substance DEA Fax Notification form
  - Pharmacy Team Leader calls the local DEA office
  - Pharmacy Team Leader faxes the completed form to the DEA office
  - Pharmacy Team Leader faxes the completed form to the SMPQ&C and the Senior Director Risk Management Services and Corporate Counsel (please see the form for the fax numbers)
  - If the loss occurred in an Ohio store, Pharmacy Team Leader calls the local Ohio Board of Pharmacy Agent and faxes the completed form to the Ohio State Board of Pharmacy
- Within 48 hours of the suspected loss
  - PDL and LP visit the pharmacy to assess the situation, confirm or refute the loss and begin investigation

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Investigating Controlled Substance Loss

After controlled substance loss has been reported and confirmed, the continuing investigation will be led by the PDL and LP. Please refer to the "Controlled Substance Loss Checklist" on GE Central for the tracking form. The steps typically include:

- Investigation to determine if any Pharmacy Team Members are involved or responsible for the loss of controlled substances
- Oversee the physical inventory by the Pharmacy Team Leader of all controlled substances (Schedule II – Schedule V) in the pharmacy to establish and end date
- Request a Control Drug Audit Spreadsheet to be created from corporate using data collected from the previous annual inventory along with ordering and dispensing information to calculate expected on-hand quantities of all Schedule II – V medications
- Conduct a controlled substance audit comparing physical inventory to the Control Drug Audit Spreadsheet
- Quantification/verification of identified loss(es)

Reporting Verified Controlled Substance Loss

Once a loss is verified, additional reporting is required by law. The pharmacy Team Leader must immediately contact the SMPQ&C and Corporate Risk Management to discuss completion of a DEA 106 Form. Specific steps are outlined below.

- Pharmacy Team Leader will submit the completed DEA 106 online and print a final copy to be filed in the Controlled Drug Box
- Pharmacy Team Leader will fax a copy of the final, submitted DEA 106 form to Pharmacy Quality and Compliance (412-968-1552) and Pharmacy Risk Management (412-967-3761)
- If necessary, the Pharmacy Team Leader will complete and submit supplemental DEA 106 forms following the above outlined procedures
- Depending on the severity of the identified loss, the SMPQ&C will notify Senior Chain of Command
- If a Giant Eagle Team Member is involved, LP will notify appropriate Retail HR personnel and will work together to determine impact on employment
- LP will notify any required law enforcement or Board of Pharmacy in PA, MD or WV

Appendix

Giant Eagle References

Additional information on Giant Eagle Requirements can be found on GE Central in the "Compliance" folder. To access the folder:

- Select the "View Pharmacy Library" link from the Pharmacy Dashboard in GE Central
- Select the "Compliance" folder
- Select the "Controlled Substance Compliance" folder
- Select the required form

Legal References

Links to Pharmacist Manual
Links to Ohio Loss Reporting
Links to State Boards and appropriate laws, codes, etc.
Link to OARRS